DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 7, 2014

EMSI
% Cherita James
M Squared Associates, Inc.
815 King St, Suite 206
Alexandria, VA 22314

Re: K140467
Trade/Device Name: Flex-MT+
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: August 20, 2014
Received: August 22, 2014

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140467

Device Name
Flex-MT +

Indications for Use *(Describe)*

TENS - Transcutaneous Nerve Stimulation
- Symptomatic relief of chronic intractable pain
- Post traumatic and post surgical pain relief

EMS - Electrical Muscle Stimulation
- Relaxation of muscle spasm
- Increasing local blood circulation
- Muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increase range of motion

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.92 for EMSI's Flex-MT + 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: EMSI
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Tampa, Florida 33619
Ph: 813-471-0129
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Registration Number: 3003573572

Contact: M Squared Associates, Inc.
Cherita James
815 King Street, Suite 206
Alexandria, VA 22314
Ph. 703-562-9800 Ext 257
Fax. 703-562-9797

Date of Submission: September 30, 2014

Proprietary Name: **Flex-MT +**

Common Name: Powered Muscle Stimulator, Transcutaneous Nerve Stimulator

Regulatory Class: II

Regulation: 21 CFR 890.5850, 21 CFR 882.5890

Panel: Physical Medicine

Product Codes: IPF, GZJ

Predicate Device(s): K083030 EMSI TENS-EMS-14 (Flex MT), K021100 EMPI 300 PV

Device Description: The **Flex-MT +** is a combination TENS and EMS device which delivers nerve or muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 patient electrodes. The device is powered by 700 mAh 4.8V Ni-

MH rechargeable battery pack. A patient compliance timer can memorize 60 sets of operation records; the total recordable time is 999 hours.

Intended Use: As prescribed by a physician for the following:

TENS- Transcutaneous Nerve Stimulation

- Symptomatic relief of chronic intractable pain
- Post traumatic and post surgical pain relief

EMS- Electrical Muscle Stimulation

- Relaxation of muscle spasm
- Increasing local blood circulation
- Muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increase range of motion

Performance Testing

The Flex-MT + is compliant with the following standards and has outputs which are within the same range as the predicate devices.

- IEC 60601-1:2005 = Corr 1:2006, Corr 2:2007 Medical Electrical Equipment - Part 1: General Requirements For Safety
- IEC 60601-1-2:2007/AC:2010 Medical Electrical Equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Test
- IEC 60601-2-10 Edition 2.0 2012-06 Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- EN 60601-1-4:1996+A1:1999 Medical device Programmable Electrical Medical Systems (PEMS);
- EN 62304：2006/AC:2008 Medical device software-Software life cycle processes.

Technical and Performance Comparison

Both the subject device and the predicate device are battery powered, handheld devices with similar unit characteristics including device controls, power supply, output modes and channels, waveforms, output voltage, current and pulse durations, as well as device material.

	Subject Device Flex-MT +	**Predicate K08303 EMSI TENS-EMS-14(Flex MT)**	**Predicate K021100 EMPI 300PV (TENS/NMES modes)**	Comment
Indication for Use	TENS- Transcutaneous Nerve Stimulation •Symptomatic relief of chronic intractable pain •Post traumatic and post surgical pain relief EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation •Muscle re-education •Prevention or retardation of disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	TENS- Transcutaneous Nerve Stimulation •Symptomatic relief of chronic intractable pain •Post traumatic and post surgical pain relief EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation •Muscle re-education •Prevention or retardation of disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	TENS- Transcutaneous Nerve Stimulation •Symptomatic relief of chronic intractable pain •Adjunctive treatment for post surgical and post trauma pain EMS- Electrical Muscle Stimulation •Relaxation of muscle spasm •Increasing local blood circulation • Re-education muscles • Retarding or preventing disuse atrophy •Prevention of venous thrombosis of the calf muscles immediately after surgery •Maintaining or increase range of motion	Same indications in the subject and predicates TENS and NMES modes.

	Subject Device Flex-MT +	**Predicate K08303 EMSI TENS-EMS-14(Flex MT)**	**Predicate K021100 EMPI 300PV**	**Comment**
4. Power Source	700 mAh 4.8V Ni-MH, rechargeable	four batteries, size AA, alkaline	Two batteries, size AA rechargeable, and charger	All devices are battery operated. The subject and

	Subject Device Flex-MT +	**Predicate K08303 EMSI TENS-EMS-14(Flex MT)**	**Predicate K021100 EMPI 300PV**	**Comment**
	battery pack and charger			EMPI devices offer a battery charger.
– Method of Line Current Isolation	n/a	n/a	n/a	NA
– Patient Leakage Current - Normal condition - Single fault condition	not measurable < 1 microamp	not measurable < 1 microamp	Unknown	The subject and EMSI predicate have the same Patient Leakage level
5. Number of Output Modes	2	2	4	The subject and EMSI predicate have the same number of channels. The EMPI predicates offers the same 2 channels, as well as 2 additional channels for their IFS and FES outputs.
6. Number of Output Channels	2	2	2	Same number and type of output channels and channel isolation.
– Synchronous or Alternating	Synchronous or Alternating	Synchronous or Alternating	Synchronous or Alternating	
– Method of Channel Isolation	Transformer	Transformer	Transformer	
7. Regulated Current or Regulated Voltage?	Regulated Voltage	Regulated voltage	Unknown	Same regulated voltage method as the EMSI predicate device.
8. Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	All devices are software controlled
9. Automatic Overload Trip?	Yes	No	Unknown	The automatic overload protection provides additional safety when operating the subject device

	Subject Device **Flex-MT +**	**Predicate K08303 EMSI TENS-EMS-14(Flex MT)**	**Predicate K021100 EMPI 300PV**	**Comment**
11. Automatic Shut Off?	Yes	Yes	Yes	Same features
12. Patient Override Control?	Yes	Yes	Yes	Same features
13. Indicator Display: On/Off Status? Low Battery? Voltage/Current Level?	 Yes Yes Yes (1-10 bars displayed)	 Yes Yes Yes (1-10 bars displayed)	 Yes Yes Yes	Same features
4. Timer Range (minutes)	5-90 minutes, or continuous	5-90 minutes, or continuous	5-99 minutes, or continuous	Minor timer difference when compared to the EMPI predicate do not affect safety or effectiveness.
15. Compliance with Voluntary Standards?	ANSI/AAMI ES1-1993 IEC 60601-1-2 as applicable	ANSI/AAMI ES1-1993 IEC 60601-1-2 as applicable	Unknown	NA
16. Compliance with 21 CFR 898?	Yes	Yes	Yes	Same features
17. Weight	156 g (including battery)	140 g	226g	Minor differences in weight and dimensions do not change device performance. Same materials.
18. Dimensions [W x H x D]	12cm x 5.4cm x 3.3cm	12 cm x 5.5cm x 2.5cm	unknown	
19. Housing Materials and Construction	plastic	plastic	plastic	

	Subject Device- Flex-MT +				**Predicate K083030 EMSI TENS-EMS-14(Flex MT)**				**Comments**
	TENS mode		**EMS mode**		**TENS mode**		**EMS mode**		Same modes
Waveform	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical	Same waveforms
Shape	Rectangular		Rectangular		Rectangular		Rectangular		Same shape
Maximum Output Voltage	43.2V @ 500Ω	43.2V @ 500Ω	43.2V @ 500Ω	43.2V @ 500Ω	41V@500 Ω	28V@500	41V @ 500 Ω	29.5V @ 500 Ω	The maximum output voltage @ 500Ω of the subject device is within the range of the EMSI and EMPI predicates. All within acceptable limits of IEC 60601-1

Maximum Output Current	86.4mA @ 500Ω	86.4mA @ 500Ω	86.4mA @ 500Ω	86.4mA @ 500Ω	82mA @ 500 Ω	56mA @ 500 Ω	82 mA @500Ω	59 mA @500Ω	Subject device has increase output current available when compared to the EMSI predicate, but within range of the EMPI predicate. All within acceptable limits of IEC 60601-1
Pulse Width per phase	50-400µsec		50-400µsec		50-300 µsec		50-300 µsec		Subject device has increased selection of pulse width option when compared to EMSI predicate, but same option as EMPI predicate.

Max Phase Duration (Positive Phase)	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms	N/A	50-300µs	N/A	50-300µs	
Max Phase Duration (Negative Phase)	2.6ms	400µs =0.4ms	2.6ms	400µs =0.4ms	-		-		
Pulse Frequency Max Duty factor	2-150 Hz 0.060	2-150 Hz 0.120	2-150 Hz 0.060	2-150 Hz 0.120	2-150Hz 0.045	2-150 Hz 0.090	2-150Hz 0.045	2-150 Hz 0.090	Same pulse frequencies available
	Subject Device- Flex-MT +				**Predicate K083030 EMSI TENS-EMS-14(Flex MT)**				
Multi-phasic waveforms	Yes	yes	Yes	yes	yes	yes	yes	yes	
Net Charge (µC per pulse)	14.6 @ 500Ω	0 (symmetrical phases result in 0)	14.6 @ 500Ω	0 (symmetrical phases)	24.5@ 500 Ω	0 (symmetrical phases)	24.6 µC @ 500 Ω	0 (symmetrical phases)	All within acceptable limits of IEC 60601-1
Maximum Phase Charge, (µ C)	14.6uC @ 500Ω	0 uC	14.6 uC @ 500Ω	0 uC @ 500Ω	24.5 @ 500 Ω	17.4 @ 500 Ω	24.6 @ 500 Ω	18 @ 500 Ω	All within acceptable limits of IEC 60601-1

Maximum Current Density, (mA/cm²)	1.83 @500Ω	2.82 @500Ω	1.83 @500Ω	2.82 @500Ω	0.26 @ 500 Ω	0.35 @ 500 Ω	0.26 @ 500 Ω	0.37 @ 500 Ω	All within acceptable limits of IEC 60601-1
Maximum Power Density, (W/cm²)	0.000858 @500Ω	0.000858 @500Ω	0.000858 @500Ω	0.000858@500 Ω	0.0105 @ 500 Ω	0.0098 @ 500 Ω	0.0105 @ 500 Ω	0.0109 @ 500 Ω	
Maximum Pulse Duration	400µs+2.6ms =0.4ms+2.6ms =3.0ms	400µs+400µs =800µs =0.8ms	400µs+2.6ms =0.4ms+2.6ms =3.0ms	400µs+400µs =800µs =0.8ms	-	-	-	-	
Additional Features (if applicable)	Patient compliance timer, battery charger				Patient compliance timer				

	Subject Device- Flex-MT +				**Predicate K021100** **EMPI 300 PV (TENS and EMS modes only)**	**Comments**
	TENS mode		**EMS mode**		**TENS and EMS mode**	Same modes
Waveform	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic	Biphasic symmetrical	Asymmetrical biphasic, Biphasic symmetrical	Same waveforms
Shape	Rectangular		Rectangular		Rectangular	Same shape
Maximum Output Voltage	43.2V @ 500Ω	43.2V @ 500Ω	43.2V @ 500Ω	43.2V @ 500Ω	50V@500 Ω	The maximum output voltage of the subject device is within the range of the EMSI and EMPI predicates. All within acceptable limits of IEC 60601-1
Maximum Output Current	86.4mA @ 500Ω	86.4mA @ 500Ω	86.4mA @ 500Ω	86.4mA @ 500Ω	100mA @ 500 Ω	The maximum output current of the subject device is within the range of the EMSI and EMPI predicates. All within acceptable limits of IEC 60601-1
Pulse Width per phase	50-400 µsec		50-400 µsec		50-400 µsec	Same range
Max Phase Duration (Positive Phase)	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms	400µs =0.4ms	-	
Max Phase Duration (Negative Phase)	2.6ms	400µs =0.4ms	2.6ms	400µs =0.4ms	-	

Phase duration	50-400 µsec	50-400 µsec	50-400 µsec	50-400 µsec	Unknown	---
Net Charge (µC per pulse)	14.6 @500Ω	0 (symmetrical phases result in 0)	14.6 @500Ω	0 (symmetrical phases)	Unknown	---
Maximum Phase Charge, (µ C)	14.6uC @ 500Ω	0uC @ 500 Ω	14.6 uC @ 500Ω	0 uC @ 500Ω	40 uC @ 500 Ω	All within acceptable limits of IEC 60601-1
Maximum Current Density, (mA/cm²)	14.6 @500Ω	0@500Ω	14.6 @500Ω	0@500Ω	0.84 @ 500 Ω 2"square electrode	All within acceptable limits of IEC 60601-1
Maximum Power Density, (W/cm²)	0.000858W/cm2 @500Ω	0.000858 W/cm2 @500Ω	0.000858 W/cm2 @500Ω	0.000858 W/cm2 @500Ω	0.0088W/cm2 @ 500 Ω 2"square electrode	All within acceptable limits to avoid thermal burn.
Maximum Pulse Duration	400µs+2.6ms =0.4ms+2.6ms =3.0ms	400µs+400µs =800µs =0.8ms	400µs+2.6ms =0.4ms+2.6ms =3.0ms	400µs+400µs =800µs =0.8ms	-	-
Additional Features (if applicable)	Patient compliance timer, battery charger				Battery charger	Same feature

Clinical Data: No clinical study data is provided in support of this submission.

Substantial Equivalence

Based on the Flex-MT+ and the predicate device technical characteristics, performance, and indications for use, the subject device is substantially equivalent to the EMSI Flex MT and the EMPI 300PV. As detailed in the tables above, the differences between the subject and predicate devices do not adversely impact the FlexMT+ safety and effectiveness for it's intended use, or it's substantial equivalence to the predicates.